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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,637	ARAM ET AL.	
	Examiner	Art Unit	
	Kandasamy Thangavelu	2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This communication is in response to the Applicants' Response dated June 8, 2007. Claims 1-6, 10, 13-14, 18, 20-23, 32 and 38 were amended. Claim 44 was added. Claims 1-4 of the application are pending. This office action is made non-final.

Claim Objections

2. The following is a quotation of 37 C.F.R § 1.75 (d)(1):

> The claim or claims must conform to the invention as set forth in the remainder of the specification and terms and phrases in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.

3. Claims 32, 34, 35, 36, 38, 40, 41 and 42 are objected to because of the following informalities:

Claim 32, Line 4, "to group image studies according to range of motion" appears to be incorrect and it appears that it should be "to group image data according to range of motion".

Claim 32, Lines 8-9, "in at least one group of image studies" appears to be incorrect and it appears that it should be "in at least one group of image data".

Claim 34, Lines 2-3, "to group the joint motion image studies into sets" appears to be incorrect and it appears that it should be "to group the joint motion image data into sets".

Claim 35, Line 3, "in the image studies" appears to be incorrect and it appears that it should be "in the image data".

Claim 36, Lines 3-4, "at least one of the joint motion image studies correlated" appears to be incorrect and it appears that it should be "at least one of the joint motion image data correlated".

Claim 38, Lines 3-4, "to group image studies according to range of motion" appears to be incorrect and it appears that it should be "to group image data according to range of motion".

Claim 38, Line 7, "in at least one group of image studies" appears to be incorrect and it appears that it should be "in at least one group of image data".

Claim 40, Line 4, "grouping the joint motion image studies into sets" appears to be incorrect and it appears that it should be "grouping the joint motion image data into sets".

Claim 41, Line 3, "in the image studies" appears to be incorrect and it appears that it should be "in the image data".

Claim 42, Lines 3-4, "at least one of the joint motion image studies correlated" appears to be incorrect and it appears that it should be "at least one of the joint motion image data correlated".

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2, 4, 16, 19, 20 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5.1 Clam 2 states in part, "a dynamic response data analyzer for receiving the dynamic response data and generating differential dimensional data for modifying the one set of model data in response to the dynamic response data". The specification states at Page 26, Lines 5-11 that "the same forces that caused the movement captured in the joint image data of database may be used in the simulator to ... provide a benchmark for dynamic response data comparisons; the differences between the response data generated by the kinematic model simulator and the response data used by the patient model simulator may be used to generate differential data for modifying the implant model". However, the specification does not describe anywhere how to compute the differential data knowing the response data generated by the kinematic model simulator and the response data used by the patient model simulator. The applicants are directed to show where in the specification a method of computing the differential data from the response

data generated by the kinematic model simulator and the response data used by the patient model simulator is described.

5.2 Claim 4 states in part, "the dynamic response data analyzer determines whether a set of model data that generates dynamic response data meets an acceptance parameter". The specification does not describe anywhere what an acceptance parameter is and what is meant by determining whether a set of model data that generates dynamic response data meets an acceptance parameter. An acceptance parameter could be a stress, a strain, a range of movement or a degree of rotation in the joint. What is meant by meeting an acceptance parameter? The applicants are directed to show where in the specification the acceptance parameter is described and the term "meeting the acceptance parameter" is explained.

5.3 Claim 16 states in part, "the dynamic response data analyzer generates a set of differential data to alter the set of model data". As explained in Paragraph 5.1 above, the specification does not describe anywhere how to compute the differential data knowing the response data generated by the kinematic model simulator and the response data used by the patient model simulator.

5.4 Claim 19 states in part, "generating differential dimensional data for modifying the set of model data in response to the dynamic response data". As explained in Paragraph 5.1 above, the specification does not describe anywhere how to compute the differential data knowing the

response data generated by the kinematic model simulator and the response data used by the patient model simulator.

5.5 Claim 20 states in part, "determining whether a set of implant model data that generates dynamic response data meets an acceptance parameter". As explained in Paragraph 5.2 above, the specification does not describe anywhere what an acceptance parameter is and what is meant by determining whether a set of implant model data that generates dynamic response data meets an acceptance parameter.

5.6 Claim 31 states in part, "generating a set of differential dimensional data from the identified conditional parameter to alter the model data". The specification does not describe anywhere how to compute the differential data knowing the identified conditional parameter to alter the model data.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 18, 19, 34, 36, and 40-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is because these claims use terms that have no antecedent bases.

In claim 1, Line 15, "the dynamic response" has no antecedent basis.

In claim 18, Line 11, "the dynamic response" has no antecedent basis.

In claim 19, Line 5, "the kinematic model" has no antecedent basis.

In claim 34, Lines 2-3, "the joint motion image studies" has no antecedent basis. Claim 32 only refers to image studies.

In claim 34, Line 3, "the degree of motion" has no antecedent basis.

In claim 36, Lines 1-2 and Line 3, "the motion versus time response data" and "the motion versus time response data" have no antecedent bases.

In claim 36, Line 3, "the joint motion image studies" has no antecedent basis. Claim 32 only refers to image studies.

In claim 40, Line 4, "the joint motion image studies" has no antecedent basis. Claim 38 only refers to image studies.

In claim 40, Lines 4-5, "the degree of motion" has no antecedent basis.

In claim 41, Line 1, "the analysis of anthropometric data" has no antecedent basis.

In claim 42, Line 1, "the analysis of joint motion data" has no antecedent basis, since there is only joint motion image data and not joint motion data.

In claim 42, Lines 2 and Line 3, "the motion versus time response data" and "the motion versus time response data" have no antecedent bases.

In claim 42, Lines 3-4, "the joint motion image studies" has no antecedent basis. Claim 32 only refers to image studies.

In claim 43, Line 1, "the joint motion data" has no antecedent basis.

In claim 44, Lines 4-5, "the kinematic model" has no antecedent basis.

8. Claim 1-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is because the claims use vague and indefinite terms making the claims indefinite.

8.1 Claim1, Lines 14-16 state, "the kinematic model simulator generates dynamic response data corresponding to the set of model data whereby the dynamic response of an artificial implant corresponding to the set of model data may be evaluated".

The use of the term "the set of model data may be evaluated" is vague and indefinite. It does not state that the set of model data is evaluated.

The terms "dynamic response data" and "the dynamic response" are vague and indefinite. While the specification may describe these terms and the Examiner is supposed to use the specification to interpret the meaning of the terms, the Examiner is required to give wide interpretation of the claim and is not allowed to read the limitations from the specification into the claims. The dynamic response data could by any one of stress, strain, displacement, velocity of motion, acceleration, degree of rotation, torque, heat produced etc. Unless the applicant states what he meant by "dynamic response data" and "the dynamic response", one of ordinary skill in

the art will not know which one of the dozen parameters the applicant is claiming as "dynamic response data" and "the dynamic response".

8.2 Claim 2, Lines 4-6 state, "in response to the dynamic response data indicating that implantation of the artificial implant corresponding to the set of model data produces a conditional parameter in the kinematic model". The term "conditional parameter" is vague and indefinite. While the specification may describe this term and the Examiner is supposed to use the specification to interpret the meaning of the term, the Examiner is required to give wide interpretation of the claim and is not allowed to read the limitations from the specification into the claims. The conditional parameter could by any one of stress, strain, displacement, velocity of motion, acceleration, degree of rotation, torque, heat produced etc. Unless the applicant states what he meant by "conditional parameter", one of ordinary skill in the art will not know which one of the dozen parameters the applicant is claiming as "conditional parameter". It is not clear if the applicant meant "a conditional parameter" or "a value of a conditional parameter".

8.3 Claim 4 states, "the dynamic response data analyzer determines whether a set of model data that generates dynamic response data meets an acceptance parameter; and

the set of model data being stored for later use in fabricating an implant that corresponds to the set of model data". It is vague as to if all set of model data are stored for later use in fabricating an implant or only the set of model data that generates dynamic response data meets an acceptance parameter.

8.4 Claim 17 states, "analyzing joint motion image data studies to group the studies into sets that are correlated by the degree of motion demonstrated during a particular activity". The term, "sets that are correlated by the degree of motion" is vague and indefinite. What is meant by degree of motion? In engineering, a motion or movement is measured by distance moved, velocity and acceleration. The rotation of a limb can be measured by the degree of rotation. However, there is no degree of motion that an expert engineer can understand. What is this language, a layman's language for some loose concept? The applicants are directed to explain this language and show where this language is described in the specification. The applicants are also directed to provide evidence of use of degree of motion in his discipline.

The term "sets that are correlated by the degree of motion" has no meaning. You cannot correlate using one variable alone. You need two variables, so the correlation between them can be identified.

8.5 Claim 18, Lines 10-12 state, "joint to generate dynamic response data corresponding to the set of implant model data whereby the dynamic response of an artificial implant corresponding to the set of implant model data may be evaluated".

The use of the term "the set of implant model data may be evaluated" is vague and indefinite. It does not state that the set of implant model data is evaluated.

The terms "dynamic response data" and "the dynamic response" are vague and indefinite. While the specification may describe these terms and the Examiner is supposed to use the specification to interpret the meaning of the terms, the Examiner is required to give wide interpretation of the claim and is not allowed to read the limitations from the specification into

the claims. The dynamic response data could by any one of stress, strain, displacement, velocity of motion, acceleration, degree of rotation, torque, heat produced etc. Unless the applicant states what he meant by "dynamic response data" and "the dynamic response", one of ordinary skill in the art will not know which one of the dozen parameters the applicant is claiming as "dynamic response data" and "the dynamic response".

8.6 Claim 19, Lines 4-6 state, "the dynamic response data indicating that the artificial implant corresponding to the set of implant model data produces a conditional parameter in the kinematic model". The term "conditional parameter" is vague and indefinite. While the specification may describe this term and the Examiner is supposed to use the specification to interpret the meaning of the term, the Examiner is required to give wide interpretation of the claim and is not allowed to read the limitations from the specification into the claims. The conditional parameter could by any one of stress, strain, displacement, velocity of motion, acceleration, degree of rotation, torque, heat produced etc. Unless the applicant states what he meant by "conditional parameter", one of ordinary skill in the art will not know which one of the dozen parameters the applicant is claiming as " a conditional parameter". It is not clear if the applicant meant "a conditional parameter" or "a value of a conditional parameter".

8.7 Claim 31, Lines 2-5 state, "generating a set of differential dimensional data from the identified conditional parameter to alter the model data so that the likelihood of the conditional parameter occurring from an implantation of an artificial joint corresponding to the set of model data is reduced". The term "conditional parameter" is vague and indefinite. While the

specification may describe this term and the Examiner is supposed to use the specification to interpret the meaning of the term, the Examiner is required to give wide interpretation of the claim and is not allowed to read the limitations from the specification into the claims. The conditional parameter could by any one of stress, strain, displacement, velocity of motion, acceleration, degree of rotation, torque, heat produced etc. Unless the applicant states what he meant by "conditional parameter", one of ordinary skill in the art will not know which one of the dozen parameters the applicant is claiming as " a conditional parameter". It is not clear if the applicant meant "a conditional parameter" or "a value of a conditional parameter".

8.8 Claim 32, Lines 4-5 state, "to group image studies according to range of motion and activity". The term "studies" is not defined and therefore is vague and indefinite. Therefore, "grouping image studies according to range of motion and activity" is vague and indefinite.

8.9 Claim 32, Lines 12-14 state, "a kinematic model simulator for generating dynamic response data corresponding to images of a simulation generated by the kinematic model simulator". The term "dynamic response data" is vague and indefinite. While the specification may describe this term and the Examiner is supposed to use the specification to interpret the meaning of the term, the Examiner is required to give wide interpretation of the claim and is not allowed to read the limitations from the specification into the claims. The dynamic response data could by any one of stress, strain, displacement, velocity of motion, acceleration, degree of rotation, torque, heat produced etc. Unless the applicant states what he meant by "dynamic

response data", one of ordinary skill in the art will not know which one of the dozen parameters the applicant is claiming as "dynamic response data".

8.10 Claim 34 states, "analysis on the joint motion image data to group the joint motion image studies into sets that are correlated by the degree of motion". The term, "sets that are correlated by the degree of motion" is vague and indefinite. What is meant by degree of motion? In engineering, a motion or movement is measured by distance moved, velocity and acceleration. The rotation of a limb can be measured by the degree of rotation. However, there is no degree of motion that an expert engineer can understand. What is this language, a layman's language for some loose concept? The applicants are directed to explain this language and show where this language is described in the specification. The applicants are also directed to provide evidence of use of degree of motion in his discipline.

The term "sets that are correlated by the degree of motion" has no meaning. You cannot correlate using one variable alone. You need two variables, so the correlation between them can be identified.

8.11 Claim 38, Lines 3-4 state, "to group image studies according to range of motion and activity". The term "studies" is not defined and therefore is vague and indefinite. Therefore, "grouping image studies according to range of motion and activity" is vague and indefinite.

8.12 Claim 38, Lines 10-11 state, "simulating a kinematic model using the generated artificial implant model to generate dynamic response data". The term "dynamic response data" is vague

and indefinite. While the specification may describe this term and the Examiner is supposed to use the specification to interpret the meaning of the term, the Examiner is required to give wide interpretation of the claim and is not allowed to read the limitations from the specification into the claims. The dynamic response data could by any one of stress, strain, displacement, velocity of motion, acceleration, degree of rotation, torque, heat produced etc. Unless the applicant states what he meant by "dynamic response data", one of ordinary skill in the art will not know which one of the dozen parameters the applicant is claiming as "dynamic response data".

8.13 Claim 40 states, "grouping the joint motion image studies into sets that are correlated by the degree of motion". The term, "sets that are correlated by the degree of motion" is vague and indefinite. What is meant by degree of motion? In engineering, a motion or movement is measured by distance moved, velocity and acceleration. The rotation of a limb can be measured by the degree of rotation. However, there is no degree of motion that an expert engineer can understand.

The term "sets that are correlated by the degree of motion" has no meaning. You cannot correlate using one variable alone. You need two variables, so the correlation between them can be identified.

8.14 Claims rejected but not specifically addressed are rejected because of their dependence on rejected claims.

8.15 The claims have been written using too many vague and indefinite terms making all the claims not allowable. These claims will never be allowed by the senior specialists' team reviewing the application for allowance. Any amount of argument (like a 40 page argument) will not advance the application towards allowance. If the applicants intend to get a patent for this application, they are advised to carefully read the detailed description in the specification and rewrite the claims eliminating the vague and indefinite language pointed to in Paragraphs 8.1 through 8.13.

9. Claims 1-17 and 32-37 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are:

9.1 Claim 1 states in the preamble, "A system for designing joint artificial implant components". Then it lists the limitations,

an anthropometric data analyzer for receiving data representative of a plurality of joints ... and analyzing the received data to identify a plurality of geometric dimensions and a range of values for the identified dimensions;

an implant model generator for receiving the identified geometric dimensions and the range of values for the identified dimensions and generating at least one set of model data ... from the range of values for the identified dimensions;

a kinematic model simulator for receiving the set of model data and incorporating the received set of model data in a kinematic model ... so that the kinematic model simulator

generates dynamic response data ... whereby the dynamic response of an artificial implant corresponding to the set of model data may be evaluated;

a database for storing the dynamic response data.

While the kinematic model simulator generates dynamic response data, none of the elements deal with designing joint artificial implant components. Therefore the system should include an element that uses the dynamic response data, and designs joint artificial implant components.

9.2 Claim 32 states in the preamble, "A system for developing solid model data from joint motion image data". Then it lists the limitations,

a motion data analyzer for analyzing joint motion image data for a plurality of joints ...;

an anthropometric data analyzer for generating geometric dimensions and measurement ranges for the geometric dimensions...;

an artificial implant model generator for generating an artificial implant model from the geometric dimensions and measurement ranges;

a kinematic model simulator for generating dynamic response data corresponding to images of a simulation generated by the kinematic model simulator ...; and

a database for storage of the dynamic response data.

While the kinematic model simulator generates dynamic response data, none of the elements deal with developing solid model data. Therefore the system should include an element that uses the dynamic response data, and develops solid model data.

9.3 Claims rejected but not specifically addressed are rejected because of their dependence on rejected claims.

10. Claims 18-31 and 38-44 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

10.1 Claim 18 states in the preamble, "A method for designing joint artificial implant components". Then it lists the limitations,

analyzing anthropometric image data for a plurality of joints to identify a plurality of geometric dimensions and a range of values for the identified dimensions;

generating at least one set of implant model data representative of the identified geometric dimensions and a group of values …;

incorporating a set of implant model data in a kinematic simulation of a joint to generate dynamic response data … whereby the dynamic response of an artificial implant corresponding to the set of implant model data may be evaluated; and

storing the dynamic response data in a computer memory.

While a set of implant model data is incorporated in a kinematic simulation of a joint to generate dynamic response data, the claim does not state that dynamic response data is generated. None of the steps deal with designing joint artificial implant components. Therefore the method should include steps that generate dynamic response data, use the dynamic response data, and design joint artificial implant components.

10.2 Claim 38 states in the preamble, "A method for developing solid model data from joint motion image data". Then it lists the limitations,

analyzing joint motion image data for a plurality of joints ...;

generating geometric dimensions and measurement ranges for the geometric dimensions, ...;

generating an artificial implant model from the geometric dimensions and measurement ranges;

simulating a kinematic model using the generated artificial implant model to generate dynamic response data; and

storing the dynamic response data in a computer memory.

While the kinematic model simulation generates dynamic response data, none of the steps deal with developing solid model data. Therefore the method should include a step that uses the dynamic response data, and develops solid model data.

10.3 Claims rejected but not specifically addressed are rejected because of their dependence on rejected claims.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 1-44 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

12.1 Claim 1 states, "A system for designing joint artificial implant components comprising:

an anthropometric data analyzer …;

an implant model generator for generating at least one set of model data …;

a kinematic model simulator … the kinematic model simulator generates dynamic response data …; and

a database for storing the dynamic response data".

The claim involves a system for designing joint artificial implant. The system does not produce any useful, tangible and concrete results and therefore is not statutory and cannot be patented under 35 USC 101. To produce useful, tangible and credible results, the system should **display some of the results on a display terminal or save the results in a file** for use in

analysis and design. String the data in a database could mean storing it on paper also and it is considered not useful, tangible and concrete result.

In addition, the system as claimed comprises only software. If all parts of a system are software, then the system becomes descriptive material and is not statutory and cannot be patented under 35 USC 101. The system should include some hardware elements to be statutory and patentable. The applicants' arguments on Pages 12 and 13 of the amendment dated June 13, 2007 are rejected because the specification clearly states on Page 5, Line 2 to Page 6, Line 6 that an anthropometric data analyzer is a computer program; on Page 6, Lines 7-15 that an implant model generator is a computer program; on Page 7, Lines 17-18 that a kinematic model simulator is a computer program.

Claims 2-17 depend on claim 1 but do not produce any useful, tangible and concrete results and therefore are not statutory and cannot be patented under 35 USC 101.

12.2 Claim 18 states, "A method for designing joint artificial implant components comprising:

analyzing anthropometric image data ...;

generating at least one set of implant model data ...;

incorporating a set of implant model data in a kinematic simulation ...; and

storing the dynamic response data in a computer memory".

The claim involves a method for designing joint artificial implant components. The method does not produce any useful, tangible and concrete results and therefore is not statutory

and cannot be patented under 35 USC 101. To produce useful, tangible and credible results, the **method should display some results on a display terminal or save the results in a file** for use in analysis and design. Storing data in a computer's memory is not considered as useful, tangible and concrete result, since the data in the memory will be lost when the computer stops. In addition, the method is not claimed as computer implemented and therefore could be implemented on a paper. Such method is not patentable under 35 USC 101.

Claims 19-31 and 44 depend on claim 18 but do not produce any useful, tangible and concrete results and therefore are not statutory and cannot be patented under 35 USC 101.

12.3 Claim 32 states, "A system for developing solid model data from joint motion image data comprising:

a motion data analyzer for analyzing joint motion image data ...;

an anthropometric data analyzer for generating geometric dimensions ...;

an artificial implant model generator for generating an artificial implant model ...; and

a database for storage of the dynamic response data".

The claim involves a system for developing solid model data from joint motion image data. The system does not produce any useful, tangible and concrete results and therefore is not statutory and cannot be patented under 35 USC 101. To produce useful, tangible and credible results, the system should **display some of the results on a display terminal or save the results in a file** for use in analysis and design. String the data in a database could mean storing it on paper also and it is considered not useful, tangible and concrete result.

In addition, the system as claimed comprises only software. If all parts of a system are software, then the system becomes descriptive material and is not statutory and cannot be patented under 35 USC 101. The system should include some hardware elements to be statutory and patentable. The applicants' arguments on Pages 12 and 13 of the amendment dated June 13, 2007 are rejected because the specification clearly states On Page 5, L2 to Page 6, L6 that an anthropometric data analyzer is a computer program; on Page 6, L7-15 that an implant model generator is a computer program; on Page 7, L17-18 that a kinematic model simulator is a computer program.

Claims 33-37 depend on claim 32 but do not produce any useful, tangible and concrete results and therefore are not statutory and cannot be patented under 35 USC 101.

12.4 Claim 38 states, "A method for developing solid model data from joint motion image data comprising:

analyzing joint motion image data to group image studies ...;

generating an artificial implant model from the geometric dimensions ...;

simulating a kinematic model using the generated artificial implant model...; and

storing the dynamic response data in a computer memory".

The claim involves a method for developing solid model data from joint motion image data. The method does not produce any useful, tangible and concrete results and therefore is not statutory and cannot be patented under 35 USC 101. To produce useful, tangible and credible

results, the **method should display some results on a display terminal or save the results in a file** for use in analysis and design. Storing data in a computer's memory is not considered as useful, tangible and concrete result, since the data in the memory will be lost when the computer stops. In addition, the method is not claimed as computer implemented and therefore could be implemented on a paper. Such method is not patentable under 35 USC 101.

Claims 39-43 depend on claim 38 but do not produce any useful, tangible and concrete results and therefore are not statutory and cannot be patented under 35 USC 101.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 18-33 and 38-39 are rejected under 35 U.S.C. § 102(b) as being anticipated by **DiGioia, III et al.** (U.S. Patent 6,205,411).

14.1 **DiGioia, III et al.** teaches computer assisted surgery planner and intra-operative guidance system. Specifically, as per claim 18, **DiGioia, III et al.** teaches a method for designing joint artificial implant components (Abstract, L1-2; CL4, L67 to CL5, L1; CL7, L17-18), comprising:

analyzing anthropometric image data for a plurality of joints to identify a plurality of geometric dimensions and a range of values for the identified dimensions (Fig. 2, Item 40; CL2, L56-58; CL6, L58-61);

generating at least one set of implant model data representative of the identified geometric dimensions and a group of values with the range of values for the identified dimensions (Abstract, L4-5; Fig. 1, Item 12; Fig. 2, Item 42; CL2, L58-61; CL4, L67 to CL5, L1; CL5, L64-67; CL6, L58-61; CL7, L17-18);

incorporating a set of implant model data in a kinematic simulation of a joint (Abstract, L5-7; Fig. 1, Item 14; Fig. 2, Item 44; CL5, L67 to CL6, L5), joint to generate dynamic response data corresponding to the set of implant model data (Fig. 2, Item 44 and Item 46; CL2, L67 to CL3, L4; CL5, L1-3; CL6, L2-3; CL7, L19-26; CL7, L46-53), whereby the dynamic response of an artificial implant corresponding to the set of model data may be evaluated (Fig. 2, Item 48; CL5, L64 to CL6, L5; CL1, L48-50; CL2, L67 to CL3, L4; CL3, L28-31; CL7, L46-53); and

storing the dynamic response data in a computer memory (Fig. 1; CL6, L8-23).

Per claim 19: **DiGioia, III et al.** teaches generating differential dimensional data for modifying the set of model data in response to the dynamic response data (CL3, L5-9; CL4, L53-56; CL4, L67 to CL5, L3; CL6, L3-4; CL7, L19-26), indicating that implantation of the artificial implant corresponding to the set of model data produces a conditional parameter in the kinematic model (CL1, L45-50; CL2, L67 to CL3, L4; CL3, L28-31; CL4, L67 to CL5, L3).

Per claim 44: **DiGioia, III et al.** teaches incorporating the differential dimensional data to generate a second set of implant model data (CL3, L5-9; CL4, L53-56; CL4, L67 to CL5, L3; CL6, L3-4; CL7, L19-26);

incorporating the second set of implant model data within the kinematic model to generate a second set of dynamic response data (Abstract, L4-5; Fig. 1, Item 12; Fig. 2, Item 42; CL2, L58-61; CL4, L67 to CL5, L1; CL5, L64-67; CL6, L58-61; CL7, L17-18); and

determining whether differential dimensional data generated from the second set of dynamic response data indicates modification of the second set of model data (CL1, L45-50; CL2, L67 to CL3, L4; CL3, L28-31; CL4, L67 to CL5, L3).

Per claim 20: **DiGioia, III et al.** teaches determining whether a set of implant model data that generates dynamic response data meets an acceptance parameter (CL4, L53-56; CL4, L67 to CL5, L3); and storing the set of implant model data that meets the acceptance parameters for later use to fabricate an implant (Fig. 1; CL6, L8-23).

Per claims 21-22: **DiGioia, III et al.** teaches that the anthropometric data analysis includes analysis of computed tomography (CT) data for a plurality of joints; the anthropometric data analysis includes analysis of magnetic resonance image (MRI) data for a plurality of joints; (CL3, L42-46; CL6, L50-58).

Per claim 23: **DiGioia, III et al.** teaches that the anthropometric data analysis includes analysis of three dimensional image data (CL6, L50-58).

Per claims 24 and 25: **DiGioia, III et al.** teaches that the image data analysis includes enabling an operator to select a feature in static image data for defining a geometric dimension and measuring the selected geometric dimension; and the three dimensional data analysis includes using a computer program that measures terrain topographic features (CL7, L1-12; CL6, L50-61).

Per claim 26: **DiGioia, III et al.** teaches that the implant model data generation includes modifying the set of implant model data with image data of a joint physiology in dynamic motion (CL3, L5-9; CL4, L53-56; CL4, L67 to CL5, L3; CL6, L3-4; CL7, L19-26; CL3, L28-31; CL6, L50-58).

Per claim 27: **DiGioia, III et al.** teaches that the implant model data modification includes modification using dynamic motion image data of a joint compiled by taking fluoroscopic images of a joint in motion (CL3, L28-31; CL4, L53-56; CL7, L46-53; CL8, L59-63; CL6, L50-58).

Per claim 28: **DiGioia, III et al.** teaches that the kinematic model simulation includes applying emulation force vectors to the implant model data (Fig. 2, Item 48; CL5, L64 to CL6, L5; CL1, L48-50; CL2, L67 to CL3, L4; CL3, L28-31; CL6, L8-12; CL7, L46-53).

Per claim 29: **DiGioia, III et al.** teaches that the kinematic model simulation includes: generating motion response data in the time domain (CL3, L28-31; CL4, L53-56; CL7, L46-53).

Per claim 30: **DiGioia, III et al.** teaches that the dynamic response data analysis includes identifying a conditional parameter (CL1, L45-50; CL2, L67 to CL3, L4; CL3, L28-31; CL4, L67 to CL5, L3).

Per claim 31: **DiGioia, III et al.** teaches that the dynamic response data analysis includes generating a set of differential dimensional data from the identified conditional parameter to alter the model data (CL3, L5-9; CL4, L53-56; CL4, L67 to CL5, L3; CL6, L3-4; CL7, L19-26), so that the likelihood of the conditional parameter occurring from an implantation of an artificial joint corresponding to the set of model data is reduced (CL1, L45-50; CL2, L67 to CL3, L4; CL3, L28-31; CL4, L67 to CL5, L3).

14.2 As per claim 32, **DiGioia, III et al.** teaches a system for developing solid model data from joint motion image data (Abstract, L4-5; Fig. 1, Item 12; Fig. 2, Item 42; CL2, L58-61; CL4, L67 to CL5, L1; CL5, L64-67; CL6, L58-61; CL7, L17-18), comprising:

a motion data analyzer for analyzing joint motion image data to group image studies according to range of motion and activity (CL3, L28-31; CL4, L53-56; CL7, L46-53);

an anthropometric data analyzer for generating geometric dimensions and measurement ranges for the geometric dimensions (Fig. 2, Item 40; CL2, L56-58; CL6, L58-61), the geometric

dimensions and measurement ranges corresponding to the image studies in at least one group of image studies (Fig. 2, Item 40; CL2, L56-58; CL6, L58-61, CL6, L50-61);

an artificial implant model generator for generating an artificial implant model from the geometric dimensions and measurement ranges (Abstract, L4-5; Fig. 1, Item 12; Fig. 2, Item 42; CL2, L58-61; CL4, L67 to CL5, L1; CL5, L64-67; CL6, L58-61; CL7, L17-18); and

a kinematic model simulator (Abstract, L5-7; Fig. 1, Item 14; Fig. 2, Item 44; CL5, L67 to CL6, L5).

Per claim 33: **DiGioia, III et al.** teaches that the motion data analyzer receives fluoroscopic image data of a plurality of joints in motion (CL8, L59-63).

14.3 As per Claims 38 and 39, these are rejected based on the same reasoning as Claims 32 and 33, supra. Claims 38 and 39 are method claims reciting the same limitations as Claims 32 and 33 as taught throughout by **DiGioia, III et al.**

Response to Arguments

15. Applicants' arguments with respect to 35 USC 102 (b) rejections with respect to claims 1-17 are moot in view of claim amendments made. Claim rejections of claims 1-17 under 35 USC 102 (b) and 103 (a) are withdrawn in response to Applicants' amendments. Claim rejections under 35 USC 102 (b) for claims 18-44 are maintained since the amendments do not include a plurality of patients. Claim rejections under 35 USC 101 are maintained, since the

claim amendments do not meet the 101 requirements. Additional claim rejections under 35 USC 112 First and Second paragraphs are included in this Office Action.

15.1 As per the applicants' argument that "the subsystems set forth in the claims are described as computer programs executing on computer systems; exemplary computers are identified in the specification along with interfaces for communicating image data with CT, MRI, and other image sources as well as displays for generated images; thus, claims 1 and 32 set forth elements having hardware components by reciting the anthropometric data analyzer, implant model generator, and kinematic model simulator, and motion data analyzer; these elements modify and display data signals and, therefore, constitute statutory subject matter.; Applicants have amended the claims to include a database for storing the dynamic response data generated by the kinematic model simulator", the Examiner respectfully disagrees because the specification clearly states on Page 5, Line 2 to Page 6, Line 6 that an anthropometric data analyzer is a computer program; on Page 6, Lines 7-15 that an implant model generator is a computer program; on Page 7, Lines 17-18 that a kinematic model simulator is a computer program.

15.2 As per the applicants' argument that "the system of DiGioia is limited to a single patient's joint; as taught in DiGioia, *the* skeletal structure is obtained from the skeletal data source; the tomographic data from *the* scanned structure generated by the skeletal data source is provided to the geometric planner to produce a model of *the* skeletal structure; the models of the joint and the artificial component are used to simulate movement of *the* joint that will contain the artificial components; variations in the testing are performed to optimize size, position, and

orientation of the artificial components in *the* patient's joint; DiGioia only teaches that image data of a single joint are used with artificial joint models to construct an optimized implant for a single patient; applicants' have developed a system that avoids the customization and one-of-a-kind implant production that occurs with use of the system in DiGioia; while the variations in human anatomy present formidable obstacles to produce implants that meet the needs for a range of patients, Applicants have developed a system that analyzes image data for a plurality of joints in a group of patients to generate an implant model that may be used to fabricate a single version of an implant that meets the needs of all; the system of DiGioia cannot produce such an implant", the Examiner has withdrawn art rejections of claim 1 which uses a plurality of joints in a plurality of patients.

15.2 As per the applicants' arguments regarding art rejections of claims 2-17, the Examiner has withdrawn art rejections of claims 2-17, which use a plurality of joints in a plurality of patients.

15.3 As per the applicants' arguments regarding art rejections of claims 18- 44, the Examiner has maintained art rejections of these claims, because they do not use a plurality of joints in a plurality of patients.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 571-272-3717. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez, can be reached on 571-272-3753. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to TC 2100 Group receptionist: 571-272-2100.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

K. Thangavelu
Art Unit 2123
July 25, 2007